

## 5. 臨床検査

(測定された検査値についてはすべてご記入をお願いします。また、副作用等に関連があると思われる検査値については必ず下欄にコメントをご記入下さい。)

検査項目	貴院の 正常範囲	投与前	経過					
		月 日	8月12日	1月26日	月 日	月 日	月 日	
赤血球数 (×10 <sup>4</sup> /mm <sup>3</sup> )								
血色素量 (g/dl)								
ヘマトクリット (%)								
血小板数 (×10 <sup>4</sup> /mm <sup>3</sup> )								
白血球数 (/mm <sup>3</sup> )								
血液 白血球百分率	好塩基球 (%)	~						
	好酸球 (%)	~						
	好中球 (%)	~						
	リンパ (%)	~						
	単球 (%)	~						
赤沈 (1hr)	~							
CRP (mg/dL)	~							
	~							
	~							
肝機能	AST (GOT) (IU)	~		165	35			
	ALT (GPT) (IU)	~		365	510			
	AI-P (IU/L)	~		696	249			
	LDH (IU)	~						
	ビリルビン (mg/dL)	~						
	直接型ビリルビン (mg/dL)	~	~					
	~							
腎機能	BUN	~						
	血清クレアチニン	~						
	クレアチニン・クリアランス	~						
	~							
	~							
尿・その他	蛋白	~						
	糖	~						
	ウロビリノーゲン	~						
	沈渣 (赤・白・円)	~						
	尿量	~						
	電解質	Na (mEq/L)	~					
		K (mEq/L)	~					
		Cl (mEq/L)	~					
		Ca (mEq/L)	~					
	血圧	~						
脈拍 (回/分)	~							
	~							
	~							

臨床検査値の異常、及び本剤との因果関係等に対するコメントをご記入下さい。

厚労省 報告	なし	報告済・予定	学会・ 文献発表	なし	発表済・予定	雑誌名 _____ 誌 卷 _____ 号 _____ 学会名 _____ 学会 _____
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AST(10003543); ALT(10001844); AI-P(10001770)

## 補足データ

### 症例 No. 1

報告された有害事象名	企業評価
脳出血	不明
出血性ショック	不明
肝不全(肝硬変)	不明
敗血症性ショック	不明

#### 企業コメント：

死亡に至った肝不全（肝硬変）は、合併症であるC型肝炎による影響が強く考えられます。脳出血、出血性ショックは、合併症である血友病Aによる影響が考えられます。また出血性ショックは、大腿骨置換術後に発現しており、置換術の影響も否定できないと考えられます。MRSA感染及びそれによる敗血症性ショックは、HIV感染症を有する易感染状態の患者に偶発的に発現したと考えます。

添付資料2 規格(草案)準拠のXML形式で表された添付資料1のデータ

```
<?xml version="1.0" encoding="UTF-8" ?>
- <PORR_IN049006UV xsi:schemaLocation="urn:hl7-org:v3 Schemas/multicacheschemas/PORR_IN049006UV.xsd"
  xmlns:mif="urn:hl7-org:v3/mif" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" ITSVersion="XML_1.0"
  xmlns="urn:hl7-org:v3">
  <!-- ##### ICE E2B Mapping FDP Version ##### -->
  <id extension="JP-ABC-01-20090715" root="0.2.3.4.5.1.1" />
  <!-- @@@ M.1.4: Message Number -->
  <creationTime value="20090715161044" />
  <!-- @@@ M.1.7b: Message Date -->
  <interactionId extension="PORR_IN049006UV" root="2.16.840.1.113883.1.6" />
  <!-- HL7 V3 Interaction ID -->
  <profileId extension="6" root="0.2.1.10.1" />
  <!-- @@@ M.1.1: Message Format Version -->
  <profileId extension="6.0" root="0.2.1.10.2" />
  <!-- @@@ M.1.3: Message Format Release -->
  <processingCode code="P" />
  <!-- defines whether the message is part of a production, training, or debugging system -->
  <processingModeCode code="T" />
  <!-- defines whether the message is being set in current processing -->
  <acceptAckCode code="AL" />
  <!-- Always send an acknowledgement -->
- <receiver>
- <device classCode="DEV" determinerCode="INSTANCE">
  <id extension="RS001" root="0.2.5.6.7.1.2" />
- <asAgent classCode="AGNT">
- <representedOrganization classCode="ORG" determinerCode="INSTANCE">
  <id extension="JP-pmda" root="0.2.5.6.7" />
  <!-- @@@ M.1.6: Message Receiver Identifier -->
  </representedOrganization>
  </asAgent>
</device>
</receiver>
- <sender>
- <device classCode="DEV" determinerCode="INSTANCE">
  <id extension="SV1" root="0.2.3.4.5.1.2" />
- <asAgent classCode="AGNT">
- <representedOrganization classCode="ORG" determinerCode="INSTANCE">
  <id extension="JP-ABC-01" root="0.2.3.4.5" />
  <!-- @@@ M.1.5: Message Sender Identifier -->
  </representedOrganization>
  </asAgent>
</device>
</sender>
- <controlActProcess classCode="CACT" moodCode="EVN">
- <subject typeCode="SUBJ">
- <investigationEvent>
  <id extension="JP-ABC-01" root="0.2.999.10.2.1" />
  <!-- @@@ A.1.0.1: Sender's (Case) Safety Report Unique Identifier (Safety Report Identifier) -->
  <id extension="JP-ABC-01" root="0.2.999.10.3" />
  <!-- @@@ A.1.10.1: Worldwide unique case identification number -->
  <code code="ichicsr" codeSystem="0.2.999.5.27" />
  <text mediaType="text/plain">2005/7/9頭痛、嘔吐出現。検査目的で入院。2005/7/10全身性の痙攣出現。頭部CTにより、脳出血と診断。プロインツイ、サルナウノ投与。大腿骨頸部骨折を認め、脳出血による痙攣が原因と考えられた2005/8/11大腿骨人工関節置換術を施行。大腿骨頸部骨折は回復。2005/8/12大腿骨人工関節置換術後、血圧、意識レベルが著明に低下。出血性ショックを認めた。MAP(6単位)、血小板(20単位)輸血実施。肝不全(肝硬変)が発現。2005/8/16出血性ショックは回復。2006/1/25夜39.4度の発熱。尿路感染症を疑いリケナテプ投与。2006/1/29ワモンポに変更。2006/1/31呼吸困難、尿量低下、ショック状態となりICCUへ搬送。血液培養で、MRSAを検出し敗血症性ショックと診断し、サンビウミスン投与開始。肝不全については、肝移植も考慮したが、出血リスクが高く、MRSA感染症を併発したため不可能であった。2006/2/8敗血症性ショック改善し、ICCU退室。2006/2/20全身状態が悪化し死亡。</text>
  <!-- @@@ B.5.1: Case narrative -->
  <statusCode code="active" />
- <activityTime>
  <low value="20090709" />
  <!-- @@@ A.1.6b: Date report was first received from source -->
  </activityTime>
  <availabilityTime value="20090715" />
  <!-- @@@ A.1.7b: Date of the most recent receipt information for this report -->
  <!-- ##### B.1: Patient characteristics ##### START -->
- <subject>
- <investigativeSubject>
- <subjectPerson determinerCode="INSTANCE">
  <name>H.T.</name>
  <!-- @@@ B.1.1: Patient -->
  <administrativeGenderCode code="1" codeSystem="0.2.999.6.1" />
  <!-- @@@ B.1.5: Sex -->
  <deceasedTime value="20090704" />
  <!-- @@@ B.1.9.1b: Date of death -->
- <asIdentifiedEntity>
  <id extension="4266706" root="0.2.13.1" />
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    <!-- @@@ B.1.1.1c: Patient medical record number(s) and the source(s) of the record number
    (Hospital record number) -->
    <code code="hospitalMrn" codeSystem="0.2.999.5.12" />
  </asIdentifiedEntity>
</subjectPerson>
<!-- ##### A_ProductReportingRelevantInformation CNET ##### START -->
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="age" codeSystem="0.2.999.5.13" />
  <value unit="a" xsi:type="PQ" value="27" />
  <!-- @@@ B.1.2.2a: Age at time of onset of reaction/event (Age value) -->
  <!-- @@@ B.1.2.2b: Age at time of onset of reaction/event (Age unit) -->
</observationProcess>
</subjectOf>
- <subjectOf>
  <!-- ##### B.1.7: Relevant medical history and concurrent conditions ##### START -->
  - <organizer>
    <code code="relevantMedicalHistoryAndconcurrentConditions" codeSystem="0.2.999.5.16" />
    - <component typeCode="COMP">
      - <observationProcess moodCode="EVN">
        <code code="10062859" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70" />
        <!-- @@@ B.1.7.1.r.a.1: MedDRA version for Medical History -->
        <!-- @@@ B.1.7.1.r.a.2: Structured information (Disease / surgical procedure / etc.) -->
      </observationProcess>
    </component>
    - <component typeCode="COMP">
      - <observationProcess moodCode="EVN">
        <code code="10018937" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70" />
        <!-- @@@ B.1.7.1.r.a.1: MedDRA version for Medical History -->
        <!-- @@@ B.1.7.1.r.a.2: Structured information (Disease / surgical procedure / etc.) -->
      </observationProcess>
    </component>
    - <component typeCode="COMP">
      - <observationProcess moodCode="EVN">
        <code code="10019744" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70" />
        <!-- @@@ B.1.7.1.r.a.1: MedDRA version for Medical History -->
        <!-- @@@ B.1.7.1.r.a.2: Structured information (Disease / surgical procedure / etc.) -->
      </observationProcess>
    </component>
    - <component typeCode="COMP">
      - <observationProcess moodCode="EVN">
        <code code="10020161" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70" />
        <!-- @@@ B.1.7.1.r.a.1: MedDRA version for Medical History -->
        <!-- @@@ B.1.7.1.r.a.2: Structured information (Disease / surgical procedure / etc.) -->
      </observationProcess>
    </component>
    - <component typeCode="COMP">
      - <observationProcess moodCode="EVN">
        <code code="10066152" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70" />
        <!-- @@@ B.1.7.1.r.a.1: MedDRA version for Medical History -->
        <!-- @@@ B.1.7.1.r.a.2: Structured information (Disease / surgical procedure / etc.) -->
      </observationProcess>
      - <effectiveTime xsi:type="IVL_TS">
        <low value="20050812" />
        <!-- @@@ B.1.7.1.r.c: Start Date -->
        <high value="20050812" />
        <!-- @@@ B.1.7.1.r.f: End Date -->
      </effectiveTime>
    </component>
    - <component typeCode="COMP">
      - <observationProcess moodCode="EVN">
        <code code="concomitantTherapy" codeSystem="0.2.999.5.13" />
        <value xsi:type="BL" value="true" />
        <!-- @@@ B.1.7.3: Concomitant therapies -->
      </observationProcess>
    </component>
  </organizer>
  <!-- ##### B.1.7: Relevant medical history and concurrent conditions ##### END -->
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="reportedCauseOfDeath" codeSystem="0.2.999.5.13" />
  <value code="10019663" xsi:type="CE" codeSystemVersion="12.0"
    codeSystem="2.16.840.1.113883.6.70" />
  <!-- @@@ B.1.9.2.r.a: MedDRA version for reported cause(s) of death -->

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    <!-- @@@ B.1.9.2.r.b: Reported cause(s) of death -->
  </observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="autopsy" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="true" />
  <!-- @@@ B.1.9.3: Was autopsy done? -->
  - <sourceOf2 contextConductionInd="true" typeCode="DRIV">
    - <observationProcess moodCode="EVN">
      <code code="causeOfDeath" codeSystem="0.2.999.5.13" />
      <value code="肝臓表面は肝硬変の状態" xsi:type="CE" codeSystem="2.16.840.1.113883.6.70" />
      <!-- @@@ B.1.9.4.r.a: MedDRA version for autopsy-determined cause(s) of death -->
      <!-- @@@ B.1.9.4.r.b: Autopsy-determined cause(s) of death -->
    </observationProcess>
  </sourceOf2>
</observationProcess>
</subjectOf>
<!-- ##### B.2: Reaction(s)/Event(s) ##### START -->
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="termHighlightedByReporter" codeSystem="0.2.999.5.13" />
  <value extension="3" xsi:type="II" root="0.2.999.1.0.5" />
  <!-- @@@ B.2.1.2.1: Term highlighted by the reporter -->
</observationProcess>
</subjectOf>
<!-- ##### B.2.1.2.2: Seriousness criteria at event level (Results in death) ##### START -->
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="resultsInDeath" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="false" />
  <!-- @@@ B.2.1.2.2.a: Results in death -->
  - <sourceOf1 typeCode="REFR">
    - <actReference classCode="ACT" moodCode="EVN">
      <id extension="3" root="0.2.999.1.0.5" />
    </actReference>
  </sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="isLifeThreatening" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="false" />
  <!-- @@@ B.2.1.2.2.b: Life threatening -->
  - <sourceOf1 typeCode="REFR">
    - <actReference classCode="ACT" moodCode="EVN">
      <id extension="3" root="0.2.999.1.0.5" />
    </actReference>
  </sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="requiresInpatientHospitalization" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="false" />
  <!-- @@@ B.2.1.2.2.c: Caused/prolonged hospitalization -->
  - <sourceOf1 typeCode="REFR">
    - <actReference classCode="ACT" moodCode="EVN">
      <id extension="3" root="0.2.999.1.0.5" />
    </actReference>
  </sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="resultsInPersistentOrSignificantDisability" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="false" />
  <!-- @@@ B.2.1.2.2.d: Disabling/incapacitating -->
  - <sourceOf1 typeCode="REFR">
    - <actReference classCode="ACT" moodCode="EVN">
      <id extension="3" root="0.2.999.1.0.5" />
    </actReference>
  </sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="congenitalAnomalyBirthDefect" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="false" />
  <!-- @@@ B.2.1.2.2.e: Congenital anomaly/birth defect -->

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- <sourceOf1 typeCode="REFR">
- <actReference classCode="ACT" moodCode="EVN">
  <id extension="3" root="0.2.999.1.0.5" />
</actReference>
</sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="otherMedicallyImportantCondition" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="true" />
  <!-- @@@ B.2.1.2.2i: Other medically important condition -->
- <sourceOf1 typeCode="REFR">
- <actReference classCode="ACT" moodCode="EVN">
  <id extension="3" root="0.2.999.1.0.5" />
</actReference>
</sourceOf1>
</observationProcess>
</subjectOf>
<!-- ##### B.2.1.2.2: Seriousness criteria at event level (Results in death) ##### END -->
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="outcome" codeSystem="0.2.999.5.13" />
  <value code="3" xsi:type="CE" codeSystem="0.2.999.5.18" />
  <!-- @@@ B.2.1.6: Outcome of reaction/event at the time of last observation -->
- <sourceOf1 contextConductionInd="false" typeCode="REFR">
- <actReference classCode="ACT" moodCode="EVN">
  <id extension="3" root="0.2.999.1.0.5" />
</actReference>
</sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="termHighlightedByReporter" codeSystem="0.2.999.5.13" />
  <value extension="4" xsi:type="II" root="0.2.999.1.0.5" />
  <!-- @@@ B.2.1.2.1: Term highlighted by the reporter -->
</observationProcess>
</subjectOf>
<!-- ##### B.2.1.2.2: Seriousness criteria at event level (Results in death) ##### START -->
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="resultsInDeath" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="false" />
  <!-- @@@ B.2.1.2.2a: Results in death -->
- <sourceOf1 typeCode="REFR">
- <actReference classCode="ACT" moodCode="EVN">
  <id extension="4" root="0.2.999.1.0.5" />
</actReference>
</sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="isLifeThreatening" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="true" />
  <!-- @@@ B.2.1.2.2b: Life threatening -->
- <sourceOf1 typeCode="REFR">
- <actReference classCode="ACT" moodCode="EVN">
  <id extension="4" root="0.2.999.1.0.5" />
</actReference>
</sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="requiresInpatientHospitalization" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="false" />
  <!-- @@@ B.2.1.2.2c: Caused/prolonged hospitalization -->
- <sourceOf1 typeCode="REFR">
- <actReference classCode="ACT" moodCode="EVN">
  <id extension="4" root="0.2.999.1.0.5" />
</actReference>
</sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="resultsInPersistentOrSignificantDisability" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="false" />

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    <!-- @@@ B.2.1.2.2d: Disabling/Incapacitating -->
  - <sourceOf1 typeCode="REFR">
    - <actReference classCode="ACT" moodCode="EVN">
      <id extension="4" root="0.2.999.1.0.5" />
    </actReference>
  </sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="congenitalAnomalyBirthDefect" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="false" />
  <!-- @@@ B.2.1.2.2e: Congenital anomaly/birth defect -->
  - <sourceOf1 typeCode="REFR">
    - <actReference classCode="ACT" moodCode="EVN">
      <id extension="4" root="0.2.999.1.0.5" />
    </actReference>
  </sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="otherMedicallyImportantCondition" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="false" />
  <!-- @@@ B.2.1.2.2f: Other medically important condition -->
  - <sourceOf1 typeCode="REFR">
    - <actReference classCode="ACT" moodCode="EVN">
      <id extension="4" root="0.2.999.1.0.5" />
    </actReference>
  </sourceOf1>
</observationProcess>
</subjectOf>
<!-- ##### B.2.1.2.2: Seriousness criteria at event level (Results in death) ##### END -->
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="outcome" codeSystem="0.2.999.5.13" />
  <value code="1" xsi:type="CE" codeSystem="0.2.999.5.18" />
  <!-- @@@ B.2.1.6: Outcome of reaction/event at the time of last observation -->
  - <sourceOf1 contextConductionInd="false" typeCode="REFR">
    - <actReference classCode="ACT" moodCode="EVN">
      <id extension="4" root="0.2.999.1.0.5" />
    </actReference>
  </sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="termHighlightedByReporter" codeSystem="0.2.999.5.13" />
  <value extension="5" xsi:type="II" root="0.2.999.1.0.5" />
  <!-- @@@ B.2.1.2.1: Term highlighted by the reporter -->
</observationProcess>
</subjectOf>
<!-- ##### B.2.1.2.2: Seriousness criteria at event level (Results in death) ##### START -->
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="resultsInDeath" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="true" />
  <!-- @@@ B.2.1.2.2a: Results in death -->
  - <sourceOf1 typeCode="REFR">
    - <actReference classCode="ACT" moodCode="EVN">
      <id extension="5" root="0.2.999.1.0.5" />
    </actReference>
  </sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="isLifeThreatening" codeSystem="0.2.999.5.13" />
  <value xsi:type="BL" value="false" />
  <!-- @@@ B.2.1.2.2b: Life threatening -->
  - <sourceOf1 typeCode="REFR">
    - <actReference classCode="ACT" moodCode="EVN">
      <id extension="5" root="0.2.999.1.0.5" />
    </actReference>
  </sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
- <observationProcess moodCode="EVN">
  <code code="requiresInpatientHospitalization" codeSystem="0.2.999.5.13" />

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    <value xsi:type="BL" value="false" />
    <!-- @@@ B.2.1.2.2c: Caused/prolonged hospitalization -->
  - <sourceOf1 typeCode="REFR">
    - <actReference classCode="ACT" moodCode="EVN">
      <id extension="5" root="0.2.999.1.0.5" />
    </actReference>
  </sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
  - <observationProcess moodCode="EVN">
    <code code="resultsInPersistentOrSignificantDisability" codeSystem="0.2.999.5.13" />
    <value xsi:type="BL" value="false" />
    <!-- @@@ B.2.1.2.2d: Disabling/incapacitating -->
    - <sourceOf1 typeCode="REFR">
      - <actReference classCode="ACT" moodCode="EVN">
        <id extension="5" root="0.2.999.1.0.5" />
      </actReference>
    </sourceOf1>
  </observationProcess>
</subjectOf>
- <subjectOf>
  - <observationProcess moodCode="EVN">
    <code code="congenitalAnomalyBirthDefect" codeSystem="0.2.999.5.13" />
    <value xsi:type="BL" value="false" />
    <!-- @@@ B.2.1.2.2e: Congenital anomaly/birth defect -->
    - <sourceOf1 typeCode="REFR">
      - <actReference classCode="ACT" moodCode="EVN">
        <id extension="5" root="0.2.999.1.0.5" />
      </actReference>
    </sourceOf1>
  </observationProcess>
</subjectOf>
- <subjectOf>
  - <observationProcess moodCode="EVN">
    <code code="otherMedicallyImportantCondition" codeSystem="0.2.999.5.13" />
    <value xsi:type="BL" value="false" />
    <!-- @@@ B.2.1.2.2f: Other medically important condition -->
    - <sourceOf1 typeCode="REFR">
      - <actReference classCode="ACT" moodCode="EVN">
        <id extension="5" root="0.2.999.1.0.5" />
      </actReference>
    </sourceOf1>
  </observationProcess>
</subjectOf>
<!-- ##### B.2.1.2.2: Seriousness criteria at event level (Results in death) ##### END -->
- <subjectOf>
  - <observationProcess moodCode="EVN">
    <code code="outcome" codeSystem="0.2.999.5.13" />
    <value code="5" xsi:type="CE" codeSystem="0.2.999.5.18" />
    <!-- @@@ B.2.1.6: Outcome of reaction/event at the time of last observation -->
    - <sourceOf1 contextConductionInd="false" typeCode="REFR">
      - <actReference classCode="ACT" moodCode="EVN">
        <id extension="5" root="0.2.999.1.0.5" />
      </actReference>
    </sourceOf1>
  </observationProcess>
</subjectOf>
- <subjectOf>
  - <observationProcess moodCode="EVN">
    <code code="termHighlightedByReporter" codeSystem="0.2.999.5.13" />
    <value extension="6" xsi:type="II" root="0.2.999.1.0.5" />
    <!-- @@@ B.2.1.2.1: Term highlighted by the reporter -->
  </observationProcess>
</subjectOf>
<!-- ##### B.2.1.2.2: Seriousness criteria at event level (Results in death) ##### START -->
- <subjectOf>
  - <observationProcess moodCode="EVN">
    <code code="resultsInDeath" codeSystem="0.2.999.5.13" />
    <value xsi:type="BL" value="false" />
    <!-- @@@ B.2.1.2.2a: Results in death -->
    - <sourceOf1 typeCode="REFR">
      - <actReference classCode="ACT" moodCode="EVN">
        <id extension="6" root="0.2.999.1.0.5" />
      </actReference>
    </sourceOf1>
  </observationProcess>
</subjectOf>
- <subjectOf>
  - <observationProcess moodCode="EVN">

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    <code code="isLifeThreatening" codeSystem="0.2.999.5.13" />
    <value xsi:type="BL" value="true" />
    <!-- @@@ B.2.1.2.2b: Life threatening -->
  - <sourceOf1 typeCode="REFR">
    - <actReference classCode="ACT" moodCode="EVN">
      <id extension="6" root="0.2.999.1.0.5" />
    </actReference>
  </sourceOf1>
</observationProcess>
</subjectOf>
- <subjectOf>
  - <observationProcess moodCode="EVN">
    <code code="requiresInpatientHospitalization" codeSystem="0.2.999.5.13" />
    <value xsi:type="BL" value="false" />
    <!-- @@@ B.2.1.2.2c: Caused/prolonged hospitalization -->
    - <sourceOf1 typeCode="REFR">
      - <actReference classCode="ACT" moodCode="EVN">
        <id extension="6" root="0.2.999.1.0.5" />
      </actReference>
    </sourceOf1>
  </observationProcess>
</subjectOf>
- <subjectOf>
  - <observationProcess moodCode="EVN">
    <code code="resultsInPersistentOrSignificantDisability" codeSystem="0.2.999.5.13" />
    <value xsi:type="BL" value="false" />
    <!-- @@@ B.2.1.2.2d: Disabling/incapacitating -->
    - <sourceOf1 typeCode="REFR">
      - <actReference classCode="ACT" moodCode="EVN">
        <id extension="6" root="0.2.999.1.0.5" />
      </actReference>
    </sourceOf1>
  </observationProcess>
</subjectOf>
- <subjectOf>
  - <observationProcess moodCode="EVN">
    <code code="congenitalAnomalyBirthDefect" codeSystem="0.2.999.5.13" />
    <value xsi:type="BL" value="false" />
    <!-- @@@ B.2.1.2.2e: Congenital anomaly/birth defect -->
    - <sourceOf1 typeCode="REFR">
      - <actReference classCode="ACT" moodCode="EVN">
        <id extension="6" root="0.2.999.1.0.5" />
      </actReference>
    </sourceOf1>
  </observationProcess>
</subjectOf>
- <subjectOf>
  - <observationProcess moodCode="EVN">
    <code code="otherMedicallyImportantCondition" codeSystem="0.2.999.5.13" />
    <value xsi:type="BL" value="false" />
    <!-- @@@ B.2.1.2.2f: Other medically important condition -->
    - <sourceOf1 typeCode="REFR">
      - <actReference classCode="ACT" moodCode="EVN">
        <id extension="6" root="0.2.999.1.0.5" />
      </actReference>
    </sourceOf1>
  </observationProcess>
</subjectOf>
<!-- ##### B.2.1.2.2: Seriousness criteria at event level (Results in death) ##### END -->
- <subjectOf>
  - <observationProcess moodCode="EVN">
    <code code="outcome" codeSystem="0.2.999.5.13" />
    <value code="3" xsi:type="CE" codeSystem="0.2.999.5.18" />
    <!-- @@@ B.2.1.6: Outcome of reaction/event at the time of last observation -->
    - <sourceOf1 contextConductionInd="false" typeCode="REFR">
      - <actReference classCode="ACT" moodCode="EVN">
        <id extension="6" root="0.2.999.1.0.5" />
      </actReference>
    </sourceOf1>
  </observationProcess>
</subjectOf>
<!-- ##### B.2: Reaction(s)/Event(s) ##### END -->
<!-- ##### B.3: Results of tests and procedures relevant to the investigation of the patient
##### START -->
- <subjectOf>
  - <organizer moodCode="EVN">
    <code code="testsAndProceduresRelevantToTheInvestigation" codeSystem="0.2.999.5.16" />
    - <component typeCode="COMP">
      - <observationProcess moodCode="EVN">
        <code code="10003476" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70" />

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<!-- @@@ B.3.r.c1: Test name -->
<!-- @@@ B.3.r.c2: MedDRA version for test name -->
<effectiveTime xsi:type="SXCM_TS" value="20090630" />
<!-- @@@ B.3.r.b: Date and time -->
<value unit="5555" xsi:type="PQ" value="165" />
<!-- @@@ B.3.r.d: Test Result (Value and qualifier) - numeric -->
<!-- @@@ B.3.r.e: Unit -->
</observationProcess>
</component>
- <component typeCode="COMP">
- <observationProcess moodCode="EVN">
<code code="10001546" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70" />
<!-- @@@ B.3.r.c1: Test name -->
<!-- @@@ B.3.r.c2: MedDRA version for test name -->
<effectiveTime xsi:type="SXCM_TS" value="20090630" />
<!-- @@@ B.3.r.b: Date and time -->
<value unit="5555" xsi:type="PQ" value="365" />
<!-- @@@ B.3.r.d: Test Result (Value and qualifier) - numeric -->
<!-- @@@ B.3.r.e: Unit -->
</observationProcess>
</component>
- <component typeCode="COMP">
- <observationProcess moodCode="EVN">
<code code="10001670" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70" />
<!-- @@@ B.3.r.c1: Test name -->
<!-- @@@ B.3.r.c2: MedDRA version for test name -->
<effectiveTime xsi:type="SXCM_TS" value="20090630" />
<!-- @@@ B.3.r.b: Date and time -->
<value unit="5556" xsi:type="PQ" value="696" />
<!-- @@@ B.3.r.d: Test Result (Value and qualifier) - numeric -->
<!-- @@@ B.3.r.e: Unit -->
</observationProcess>
</component>
- <component typeCode="COMP">
- <observationProcess moodCode="EVN">
<code code="10003476" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70" />
<!-- @@@ B.3.r.c1: Test name -->
<!-- @@@ B.3.r.c2: MedDRA version for test name -->
<effectiveTime xsi:type="SXCM_TS" value="20090701" />
<!-- @@@ B.3.r.b: Date and time -->
<value unit="5555" xsi:type="PQ" value="35" />
<!-- @@@ B.3.r.d: Test Result (Value and qualifier) - numeric -->
<!-- @@@ B.3.r.e: Unit -->
</observationProcess>
</component>
- <component typeCode="COMP">
- <observationProcess moodCode="EVN">
<code code="10001546" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70" />
<!-- @@@ B.3.r.c1: Test name -->
<!-- @@@ B.3.r.c2: MedDRA version for test name -->
<effectiveTime xsi:type="SXCM_TS" value="20090701" />
<!-- @@@ B.3.r.b: Date and time -->
<value unit="5555" xsi:type="PQ" value="510" />
<!-- @@@ B.3.r.d: Test Result (Value and qualifier) - numeric -->
<!-- @@@ B.3.r.e: Unit -->
</observationProcess>
</component>
- <component typeCode="COMP">
- <observationProcess moodCode="EVN">
<code code="10001670" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70" />
<!-- @@@ B.3.r.c1: Test name -->
<!-- @@@ B.3.r.c2: MedDRA version for test name -->
<effectiveTime xsi:type="SXCM_TS" value="20090701" />
<!-- @@@ B.3.r.b: Date and time -->
<value unit="5556" xsi:type="PQ" value="249" />
<!-- @@@ B.3.r.d: Test Result (Value and qualifier) - numeric -->
<!-- @@@ B.3.r.e: Unit -->
</observationProcess>
</component>
</organizer>
</subjectOf>
<!-- ##### B.3: Results of tests and procedures relevant to the investigation of the patient
##### END -->
<!-- ##### B.4: Drug(s) Information ##### START -->
- <subjectOf>
- <organizer moodCode="EVN">
<code code="drugInformation" codeSystem="0.2.999.5.16" />
<!-- ##### Drug Information (1) ##### START -->
- <component typeCode="COMP">
- <substanceAdministrationProcess moodCode="EVN">

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<id extension="d3" root="0.2.999.1.0.5" />
- <consumable>
- <manufacturedProduct>
- <manufacturedProduct>
- <code code="123456789" codeSystemVersion="20090101"
  codeSystem="0.2.999.6.2">
  <!-- @@@ B.4.k.2.1.1a: MedID -->
  <!-- @@@ B.4.k.2.1.1b: MedID (version date) -->
  <originalText>ブンサレブ</originalText>
  <!-- @@@ B.4.k.2.2: Medical product name as reported by the primary
  source -->
</code>
- <instanceOfKind>
  <productInstanceInstance />
- <subjectOf>
- <productEvent>
  <code code="retailSupply" codeSystem="0.2.999.5.22" />
- <location>
- <serviceDeliveryLocation>
  - <location classCode="PLC">
    <code code="JP" codeSystem="1.0.3166.1.2" />
    <!-- @@@ B.4.k.2.4: Identification of the country where
    the drug was obtained -->
    </location>
  </serviceDeliveryLocation>
</location>
</productEvent>
</subjectOf>
</instanceOfKind>
</manufacturedProduct>
- <subjectOf>
- <approval>
  <id nullFlavor="NI" />
- <author>
- <territorialAuthority>
- <territory classCode="PLC">
  <code code="JP" codeSystem="1.0.3166.1.2" />
  <!-- @@@ B.4.k.3.2: Country of authorization/application -->
  </territory>
</territorialAuthority>
</author>
</approval>
</subjectOf>
</manufacturedProduct>
</consumable>
- <explanation>
- <interventionCharacterization classCode="INVSTG" moodCode="EVN">
  <code code="1" xsi:type="CE" codeSystem="0.2.999.5.21" />
  <!-- @@@ B.4.k.1: Characterization of drug role -->
</interventionCharacterization>
</explanation>
<!-- ##### B.4.k.4: Dosage Information (1) ##### START -->
- <sourceOf2 contextConductionInd="true" typeCode="COMP">
- <substanceAdministrationProcess moodCode="EVN">
  <id extension="1034" root="0.2.999.1.0.5" />
- <effectiveTime xsi:type="SXPR_TS">
- <comp xsi:type="PIVL_TS">
  <period unit="d" value="1.0" />
  <!-- @@@ B.4.k.4.r.4: number of units in the interval -->
  <!-- @@@ B.4.k.4.r.5: definition of the time interval unit -->
</comp>
- <comp operator="A" xsi:type="IVL_TS">
  <low value="20030320" />
  <!-- @@@ B.4.k.4.r.6b: Date of start of drug -->
  <high value="20090714" />
  <!-- @@@ B.4.k.4.r.7b: Date of last administration -->
</comp>
</effectiveTime>
- <doseQuantity>
- <translation code="003" value="450" codeSystemVersion="2001"
  codeSystem="0.2.999.6.7">
  <!-- @@@ B.4.k.4.r.2b: dose unit (Unit Term ID) -->
  <!-- @@@ B.4.k.4.r.2c: dose unit (Unit Term ID version date) -->
  <originalText>mg</originalText>
  <!-- @@@ B.4.k.4.r.2a: dose (unit) -->
</translation>
</doseQuantity>
- <consumable>
- <manufacturedProduct>
- <manufacturedProduct>

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- <code code="123456789" codeSystemVersion="20090101"
  codeSystem="0.2.999.6.2">
  <!-- @@@ B.4.k.2.1.1a: MedID -->
  <!-- @@@ B.4.k.2.1.1b: MedID (version date) -->
  <originalText>ブンサレブ</originalText>
  <!-- @@@ B.4.k.2.2: Medical product name as reported by the
  primary source -->
  </code>
</manufacturedProduct>
</manufacturedProduct>
</consumable>
</substanceAdministrationProcess>
</sourceOf2>
<!-- ##### B.4.k.4: Dosage Information (1) ##### END -->
<!-- ##### B.4.k.7: Indication for Use in case (1) ##### START -->
- <sourceOf2 contextConductionInd="true" typeCode="RSON">
- <observationProcess moodCode="EVN">
  <code code="indication" codeSystem="0.2.999.5.13" />
  - <value code="10050161" xsi:type="CE" codeSystemVersion="12.0"
    codeSystem="2.16.840.1.113883.6.70">
    <!-- @@@ B.4.k.7.r.2b: Indication in MedDRA terminology(LLT code) -->
    <!-- @@@ B.4.k.7.r.2a: MedDRA version for indication -->
    <originalText>HIV感染</originalText>
    <!-- @@@ B.4.k.7.r.1: drug indication as reported by the primary source -->
    ->
    </value>
  - <performer>
  - <assignedEntity>
    <code code="SourceReporter" codeSystem="0.2.999.5.7" />
    </assignedEntity>
  </performer>
  </observationProcess>
</sourceOf2>
<!-- ##### B.4.k.7: Indication for Use in case (1) ##### END -->
</substanceAdministrationProcess>
</component>
<!-- ##### Drug Information (1) ##### END -->
<!-- ##### Drug Information (2) ##### START -->
- <component typeCode="COMP">
- <substanceAdministrationProcess moodCode="EVN">
  <id extension="d4" root="0.2.999.1.0.5" />
  - <consumable>
  - <manufacturedProduct>
  - <manufacturedProduct>
  - <code code="234567891" codeSystemVersion="20090101"
    codeSystem="0.2.999.6.2">
    <!-- @@@ B.4.k.2.1.1a: MedID -->
    <!-- @@@ B.4.k.2.1.1b: MedID (version date) -->
    <originalText>ナーヘセウボ</originalText>
    <!-- @@@ B.4.k.2.2: Medical product name as reported by the primary
    source -->
    </code>
  - <instanceOfKind>
    <productInstanceInstance />
  - <subjectOf>
  - <productEvent>
    <code code="retailSupply" codeSystem="0.2.999.5.22" />
  - <location>
  - <serviceDeliveryLocation>
  - <location classCode="PLC">
    <code code="JP" codeSystem="1.0.3166.1.2" />
    <!-- @@@ B.4.k.2.4: Identification of the country where
    the drug was obtained -->
    </location>
  </serviceDeliveryLocation>
  </location>
  </productEvent>
  </subjectOf>
  </instanceOfKind>
  </manufacturedProduct>
  - <subjectOf>
  - <approval>
    <id nullFlavor="NI" />
  - <author>
  - <territorialAuthority>
  - <territory classCode="PLC">
    <code code="JP" codeSystem="1.0.3166.1.2" />
    <!-- @@@ B.4.k.3.2: Country of authorization/application -->
    </territory>
  </territorialAuthority>

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        </author>
        </approval>
        </subjectOf>
        </manufacturedProduct>
    </consumable>
- <explanation>
- <interventionCharacterization classCode="INVSTG" moodCode="EVN">
    <code code="2" xsi:type="CE" codeSystem="0.2.999.5.21" />
    <!-- @@@ B.4.k.1: Characterization of drug role -->
</interventionCharacterization>
</explanation>
<!-- ##### B.4.k.4: Dosage Information (1) ##### START -->
- <sourceOf2 contextConductionInd="true" typeCode="COMP">
- <substanceAdministrationProcess moodCode="EVN">
    <id extension="1048" root="0.2.999.1.0.5" />
    - <effectiveTime xsi:type="SXPR_TS">
        - <comp xsi:type="PIVL_TS">
            <period unit="d" value="1.0" />
            <!-- @@@ B.4.k.4.r.4: number of units in the interval -->
            <!-- @@@ B.4.k.4.r.5: definition of the time interval unit -->
        </comp>
        - <comp operator="A" xsi:type="IVL_TS">
            <low value="20040620" />
            <!-- @@@ B.4.k.4.r.6b: Date of start of drug -->
            <high value="20090620" />
            <!-- @@@ B.4.k.4.r.7b: Date of last administration -->
        </comp>
        </effectiveTime>
    - <doseQuantity>
        - <translation code="003" value="800" codeSystemVersion="2001"
            codeSystem="0.2.999.6.7">
            <!-- @@@ B.4.k.4.r.2b: dose unit (Unit Term ID) -->
            <!-- @@@ B.4.k.4.r.2c: dose unit (Unit Term ID version date) -->
            <originalText>mg</originalText>
            <!-- @@@ B.4.k.4.r.2a: dose (unit) -->
        </translation>
    </doseQuantity>
- <consumable>
- <manufacturedProduct>
    - <code code="234567891" codeSystemVersion="20090101"
        codeSystem="0.2.999.6.2">
        <!-- @@@ B.4.k.2.1.1a: MedID -->
        <!-- @@@ B.4.k.2.1.1b: MedID (version date) -->
        <originalText>ナーヘセウボ</originalText>
        <!-- @@@ B.4.k.2.2: Medical product name as reported by the
            primary source -->
    </code>
</manufacturedProduct>
</manufacturedProduct>
</consumable>
</substanceAdministrationProcess>
</sourceOf2>
<!-- ##### B.4.k.4: Dosage Information (1) ##### END -->
<!-- ##### B.4.k.7: Indication for Use in case (1) ##### START -->
- <sourceOf2 contextConductionInd="true" typeCode="RSON">
- <observationProcess moodCode="EVN">
    <code code="indication" codeSystem="0.2.999.5.13" />
    - <value code="10020161" xsi:type="CE" codeSystemVersion="12.0"
        codeSystem="2.16.840.1.113883.6.70">
        <!-- @@@ B.4.k.7.r.2b: Indication in MedDRA terminology (LLT code) -->
        <!-- @@@ B.4.k.7.r.2a: MedDRA version for indication -->
        <originalText>HIV感染</originalText>
        <!-- @@@ B.4.k.7.r.1: drug indication as reported by the primary source -->
    </value>
    - <performer>
        - <assignedEntity>
            <code code="SourceReporter" codeSystem="0.2.999.5.7" />
        </assignedEntity>
    </performer>
</observationProcess>
</sourceOf2>
<!-- ##### B.4.k.7: Indication for Use in case (1) ##### END -->
</substanceAdministrationProcess>
</component>
<!-- ##### Drug Information (2) ##### END -->
<!-- ##### Drug Information (3) ##### START -->
- <component typeCode="COMP">
- <substanceAdministrationProcess moodCode="EVN">

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<id extension="d5" root="0.2.999.1.0.5" />
- <consumable>
- <manufacturedProduct>
  - <manufacturedProduct>
    - <code code="345678912" codeSystemVersion="20090101"
      codeSystem="0.2.999.6.2">
      <!-- @@@ B.4.k.2.1.1a: MedID -->
      <!-- @@@ B.4.k.2.1.1b: MedID (version date) -->
      <originalText>イブーハ</originalText>
      <!-- @@@ B.4.k.2.2: Medical product name as reported by the primary
        source -->
    </code>
  - <instanceOfKind>
    <productInstanceInstance />
  - <subjectOf>
    - <productEvent>
      <code code="retailSupply" codeSystem="0.2.999.5.22" />
      - <location>
        - <serviceDeliveryLocation>
          - <location classCode="PLC">
            <code code="JP" codeSystem="1.0.3166.1.2" />
            <!-- @@@ B.4.k.2.4: Identification of the country where
              the drug was obtained -->
          </location>
        </serviceDeliveryLocation>
      </location>
    </productEvent>
  </subjectOf>
</instanceOfKind>
</manufacturedProduct>
- <subjectOf>
- <approval>
  <id nullFlavor="NI" />
  - <author>
    - <territorialAuthority>
      - <territory classCode="PLC">
        <code code="JP" codeSystem="1.0.3166.1.2" />
        <!-- @@@ B.4.k.3.2: Country of authorization/application -->
      </territory>
    </territorialAuthority>
  </author>
</approval>
</subjectOf>
</manufacturedProduct>
</consumable>
- <explanation>
- <interventionCharacterization classCode="INVSTG" moodCode="EVN">
  <code code="2" xsi:type="CE" codeSystem="0.2.999.5.21" />
  <!-- @@@ B.4.k.1: Characterization of drug role -->
</interventionCharacterization>
</explanation>
<!-- ##### B.4.k.4: Dosage Information (1) ##### START -->
- <sourceOf2 contextConductionInd="true" typeCode="COMP">
- <substanceAdministrationProcess moodCode="EVN">
  <id extension="1059" root="0.2.999.1.0.5" />
  - <effectiveTime xsi:type="SXPRTS">
    - <comp xsi:type="PIVL_TS">
      <period unit="h" value="12.0" />
      <!-- @@@ B.4.k.4.r.4: number of units in the interval -->
      <!-- @@@ B.4.k.4.r.5: definition of the time interval unit -->
    </comp>
    - <comp operator="A" xsi:type="IVL_TS">
      <low value="20041101" />
      <!-- @@@ B.4.k.4.r.6b: Date of start of drug -->
      <high value="20090620" />
      <!-- @@@ B.4.k.4.r.7b: Date of last administration -->
    </comp>
  </effectiveTime>
  - <doseQuantity>
    - <translation code="003" value="400" codeSystemVersion="2001"
      codeSystem="0.2.999.6.7">
      <!-- @@@ B.4.k.4.r.2b: dose unit (Unit Term ID) -->
      <!-- @@@ B.4.k.4.r.2c: dose unit (Unit Term ID version date) -->
      <originalText>mg</originalText>
      <!-- @@@ B.4.k.4.r.2a: dose (unit) -->
    </translation>
  </doseQuantity>
- <consumable>
  - <manufacturedProduct>
    - <manufacturedProduct>

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- <code code="345678912" codeSystemVersion="20090101"
  codeSystem="0.2.999.6.2">
  <!-- @@@ B.4.k.2.1.1a: MedID -->
  <!-- @@@ B.4.k.2.1.1b: MedID (version date) -->
  <originalText>イブーハ</originalText>
  <!-- @@@ B.4.k.2.2: Medical product name as reported by the
    primary source -->
  </code>
</manufacturedProduct>
</manufacturedProduct>
</consumable>
</substanceAdministrationProcess>
</sourceOf2>
<!-- ##### B.4.k.4: Doseage Information (1) ##### END -->
<!-- ##### B.4.k.7: Indication for Use in case (1) ##### START -->
- <sourceOf2 contextConductionInd="true" typeCode="RSON">
- <observationProcess moodCode="EVN">
  <code code="indication" codeSystem="0.2.999.5.13" />
  - <value code="10020161" xsi:type="CE" codeSystemVersion="12.0"
    codeSystem="2.16.840.1.113883.6.70">
    <!-- @@@ B.4.k.7.r.2b: Indication in MedDRA terminology (LLT code) -->
    <!-- @@@ B.4.k.7.r.2a: MedDRA version for indication -->
    <originalText>HIV感染</originalText>
    <!-- @@@ B.4.k.7.r.1: drug Indication as reported by the primary source -->
    ->
  </value>
  - <performer>
  - <assignedEntity>
    <code code="SourceReporter" codeSystem="0.2.999.5.7" />
  </assignedEntity>
  </performer>
  </observationProcess>
</sourceOf2>
<!-- ##### B.4.k.7: Indication for Use in case (1) ##### END -->
</substanceAdministrationProcess>
</component>
<!-- ##### Drug Information (3) ##### END -->
<!-- ##### Drug Information (4) ##### START -->
- <component typeCode="COMP">
- <substanceAdministrationProcess moodCode="EVN">
  <id extension="d6" root="0.2.999.1.0.5" />
  - <consumable>
  - <manufacturedProduct>
  - <manufacturedProduct>
    - <code code="456789123" codeSystemVersion="20090101"
      codeSystem="0.2.999.6.2">
      <!-- @@@ B.4.k.2.1.1a: MedID -->
      <!-- @@@ B.4.k.2.1.1b: MedID (version date) -->
      <originalText>サルナウノ</originalText>
      <!-- @@@ B.4.k.2.2: Medical product name as reported by the primary
        source -->
      </code>
    - <instanceOfKind>
      <productInstanceInstance />
    - <subjectOf>
      - <productEvent>
        <code code="retailSupply" codeSystem="0.2.999.5.22" />
      - <location>
        - <serviceDeliveryLocation>
          - <location classCode="PLC">
            <code code="JP" codeSystem="1.0.3166.1.2" />
            <!-- @@@ B.4.k.2.4: Identification of the country where
              the drug was obtained -->
            </location>
          </serviceDeliveryLocation>
        </location>
      </productEvent>
    </subjectOf>
  </instanceOfKind>
  </manufacturedProduct>
  - <subjectOf>
  - <approval>
    <id nullFlavor="NI" />
  - <author>
  - <territorialAuthority>
    - <territory classCode="PLC">
      <code code="JP" codeSystem="1.0.3166.1.2" />
      <!-- @@@ B.4.k.3.2: Country of authorization/application -->
    </territory>
  </territorialAuthority>

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        </author>
      </approval>
    </subjectOf>
  </manufacturedProduct>
</consumable>
- <explanation>
  - <interventionCharacterization classCode="INVSTG" moodCode="EVN">
    <code code="2" xsi:type="CE" codeSystem="0.2.999.5.21" />
    <!-- @@@ B.4.k.1: Characterization of drug role -->
  </interventionCharacterization>
</explanation>
<!-- ##### B.4.k.4: Dosage Information (1) ##### START -->
- <sourceOf2 contextConductionInd="true" typeCode="COMP">
  - <substanceAdministrationProcess moodCode="EVN">
    <id extension="10610" root="0.2.999.1.0.5" />
    - <effectiveTime xsi:type="SXPRTS">
      - <comp xsi:type="PIVL_TS">
        <period unit="m" value="1.0" />
        <!-- @@@ B.4.k.4.r.4: number of units in the interval -->
        <!-- @@@ B.4.k.4.r.5: definition of the time interval unit -->
      </comp>
      - <comp operator="A" xsi:type="IVL_TS">
        <low value="20050401" />
        <!-- @@@ B.4.k.4.r.6b: Date of start of drug -->
        <high value="20090625" />
        <!-- @@@ B.4.k.4.r.7b: Date of last administration -->
      </comp>
    </effectiveTime>
    - <doseQuantity>
      - <translation code="025" value="1000" codeSystemVersion="2001"
        codeSystem="0.2.999.6.7">
        <!-- @@@ B.4.k.4.r.2b: dose unit (Unit Term ID) -->
        <!-- @@@ B.4.k.4.r.2c: dose unit (Unit Term ID version date) -->
        <originalText>iu</originalText>
        <!-- @@@ B.4.k.4.r.2a: dose (unit) -->
      </translation>
    </doseQuantity>
    - <consumable>
      - <manufacturedProduct>
        - <manufacturedProduct>
          - <code code="456789123" codeSystemVersion="20090101"
            codeSystem="0.2.999.6.2">
            <!-- @@@ B.4.k.2.1.1a: MedID -->
            <!-- @@@ B.4.k.2.1.1b: MedID (version date) -->
            <originalText>サルナウノ</originalText>
            <!-- @@@ B.4.k.2.2: Medical product name as reported by the
              primary source -->
          </code>
        </manufacturedProduct>
      </manufacturedProduct>
    </consumable>
  </substanceAdministrationProcess>
</sourceOf2>
<!-- ##### B.4.k.4: Dosage Information (1) ##### END -->
<!-- ##### B.4.k.7: Indication for Use in case (1) ##### START -->
- <sourceOf2 contextConductionInd="true" typeCode="RSON">
  - <observationProcess moodCode="EVN">
    <code code="indication" codeSystem="0.2.999.5.13" />
    - <value code="10016080" xsi:type="CE" codeSystemVersion="12.0"
      codeSystem="2.16.840.1.113883.6.70">
      <!-- @@@ B.4.k.7.r.2b: Indication in MedDRA terminology(LLT code) -->
      <!-- @@@ B.4.k.7.r.2a: MedDRA version for indication -->
      <originalText>血友病A</originalText>
      <!-- @@@ B.4.k.7.r.1: drug indication as reported by the primary source -->
    </value>
    - <performer>
      - <assignedEntity>
        <code code="SourceReporter" codeSystem="0.2.999.5.7" />
      </assignedEntity>
    </performer>
  </observationProcess>
</sourceOf2>
<!-- ##### B.4.k.7: Indication for Use in case (1) ##### END -->
</substanceAdministrationProcess>
</component>
<!-- ##### Drug Information (4) ##### END -->
</organizer>
</subjectOf>
<!-- ##### B.4: Drug(s) Information ##### END -->

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    <!-- ##### A_ProductReportingRelevantInformation CMET ##### END -->
  </investigativeSubject>
</subject>
<!-- ##### B.1: Patient Characteristics ##### END -->
<!-- ##### A.3: Information on Sender of Case Safety Report ##### START -->
- <author>
- <assignedEntity>
  <code code="1" codeSystem="0.2.999.5.11" />
  <!-- @@@ A.3.1: Type -->
- <assignedPerson>
- <name>
  <prefix>代表取締役社長</prefix>
  <!-- @@@ A.3.3b: Person responsible for sending the report (Title) -->
  <given>--</given>
  <!-- @@@ A.3.3c: Person responsible for sending the report (Given name) -->
  <family>山田</family>
  <!-- @@@ A.3.3e: Person responsible for sending the report (Family name) -->
</name>
- <asAgent classCode="AGNT">
- <representedOrganization>
  <id extension="JP-ABC-01" root="0.2.15.1" />
  <!-- @@@ A.3.2: Sender Identifier (Sender organization) -->
</representedOrganization>
</asAgent>
</assignedPerson>
</assignedEntity>
</author>
<!-- ##### A.3: Information on Sender of Case Safety Report ##### END -->
<!-- ##### B.2: Reaction(s)/Event(s) ##### START -->
- <trigger>
- <reaction>
  <id extension="3" root="0.2.999.1.0.5" />
  <!-- For ActReference -->
  <code code="ADVERSE_REACTION" codeSystem="2.16.840.1.113883.5.4" />
- <effectiveTime xsi:type="IVL_TS">
  <low value="20090628" />
  <!-- @@@ B.2.1.3b: Date of start of reaction/event -->
</effectiveTime>
- <value code="10008111" xsi:type="CE" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70">
  <!-- @@@ B.2.1.1.a: MedDRA version for reaction/event -->
  <!-- @@@ B.2.1.1.b: Reaction/event in MedDRA terminology -->
  <originalText mediaType="text/plain">脳出血</originalText>
  <!-- @@@ B.2.1.0: Reaction/event as reported by primary source -->
</value>
- <location>
- <serviceDeliveryLocation>
- <location classCode="COUNTRY">
  <code code="JP" codeSystem="1.0.3166.1.2" />
  <!-- @@@ B.2.1.8: Identification of the country where the reaction/event occurred -->
</location>
</serviceDeliveryLocation>
</location>
</reaction>
</trigger>
- <trigger>
- <reaction>
  <id extension="4" root="0.2.999.1.0.5" />
  <!-- For ActReference -->
  <code code="ADVERSE_REACTION" codeSystem="2.16.840.1.113883.5.4" />
- <effectiveTime xsi:type="SXPR_TS">
- <comp xsi:type="IVL_TS">
  <low value="20090630" />
  <!-- @@@ B.2.1.3b: Date of start of reaction/event -->
  <high value="20090702" />
  <!-- @@@ B.2.1.4b: Date of end of reaction/event -->
</comp>
- <comp operator="A" xsi:type="IVL_TS">
  <width unit="d" value="3" />
  <!-- @@@ B.2.1.5a: Duration of reaction/event -->
  <!-- @@@ B.2.1.5b: Duration of reaction/event (Duration unit) -->
</comp>
</effectiveTime>
- <value code="10049771" xsi:type="CE" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70">
  <!-- @@@ B.2.1.1.a: MedDRA version for reaction/event -->
  <!-- @@@ B.2.1.1.b: Reaction/event in MedDRA terminology -->
  <originalText mediaType="text/plain">出血性ショック</originalText>
  <!-- @@@ B.2.1.0: Reaction/event as reported by primary source -->
</value>
- <location>

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- <serviceDeliveryLocation>
- <location classCode="COUNTRY">
  <code code="JP" codeSystem="1.0.3166.1.2" />
  <!-- @@@ B.2.1.1.8: Identification of the country where the reaction/event occurred -->
</location>
</serviceDeliveryLocation>
</location>
</reaction>
</trigger>
- <trigger>
- <reaction>
  <id extension="5" root="0.2.999.1.0.5" />
  <!-- For ActReference -->
  <code code="ADVERSE_REACTION" codeSystem="2.16.840.1.113883.5.4" />
  <effectiveTime xsi:type="IVL_TS">
    <low value="20090630" />
    <!-- @@@ B.2.1.1.3b: Date of start of reaction/event -->
  </effectiveTime>
  <value code="10019663" xsi:type="CE" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70">
    <!-- @@@ B.2.1.1.a: MedDRA version for reaction/event -->
    <!-- @@@ B.2.1.1.b: Reaction/event in MedDRA terminology -->
    <originalText mediaType="text/plain">肝不全</originalText>
    <!-- @@@ B.2.1.1.0: Reaction/event as reported by primary source -->
  </value>
  <location>
  <serviceDeliveryLocation>
  <location classCode="COUNTRY">
    <code code="JP" codeSystem="1.0.3166.1.2" />
    <!-- @@@ B.2.1.1.8: Identification of the country where the reaction/event occurred -->
  </location>
  </serviceDeliveryLocation>
  </location>
  </reaction>
</trigger>
- <trigger>
- <reaction>
  <id extension="6" root="0.2.999.1.0.5" />
  <!-- For ActReference -->
  <code code="ADVERSE_REACTION" codeSystem="2.16.840.1.113883.5.4" />
  <effectiveTime xsi:type="IVL_TS">
    <low value="20090701" />
    <!-- @@@ B.2.1.1.3b: Date of start of reaction/event -->
  </effectiveTime>
  <value code="10040070" xsi:type="CE" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70">
    <!-- @@@ B.2.1.1.a: MedDRA version for reaction/event -->
    <!-- @@@ B.2.1.1.b: Reaction/event in MedDRA terminology -->
    <originalText mediaType="text/plain">敗血症性ショック</originalText>
    <!-- @@@ B.2.1.1.0: Reaction/event as reported by primary source -->
  </value>
  <location>
  <serviceDeliveryLocation>
  <location classCode="COUNTRY">
    <code code="JP" codeSystem="1.0.3166.1.2" />
    <!-- @@@ B.2.1.1.8: Identification of the country where the reaction/event occurred -->
  </location>
  </serviceDeliveryLocation>
  </location>
  </reaction>
</trigger>
<!-- ##### B.2: Reaction(s)/Event(s) ##### END -->
<!-- ##### B.4.k.9: Drug-reaction(s)/event(s) matrix ##### STRAT -->
- <trigger>
- <reaction>
  <id extension="r1" root="0.2.999.1.0.5" />
  <!-- For ActReference -->
  <code code="ADVERSE_REACTION" />
  <value code="10008111" xsi:type="CE" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70">
    <!-- @@@ B.4.k.9.r.1.a: MedDRA version for Reaction(s)/event(s) assessed -->
    <!-- @@@ B.4.k.9.r.1.b: Reaction(s)/event(s) assessed -->
  </value>
  <derivation>
  <reactionRelatedness>
    <value xsi:type="ST">不明</value>
    <!-- @@@ B.4.k.9.r.2.r.3: Result -->
  <methodCode nullFlavor="OTH">
    <originalText>全体的な観察評価</originalText>
    <!-- @@@ B.4.k.9.r.2.r.2: Method of assessment -->
  </methodCode>
  <author>
  <assignedEntity>

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- <code nullFlavor="OTH">
  <originalText>報告者</originalText>
  <!-- @@@ B.4.k.9.r.2.r.1: Source of assessment -->
</code>
</assignedEntity>
</author>
- <derivedFrom>
- <implicatedActReference>
  <id extension="d3" root="0.2.999.1.0.5" />
</implicatedActReference>
</derivedFrom>
</reactionRelatedness>
</derivation>
- <derivation>
- <reactionRelatedness>
  <value xsi:type="ST">不明</value>
  <!-- @@@ B.4.k.9.r.2.r.3: Result -->
- <methodCode nullFlavor="OTH">
  <originalText>全体的な観察評価</originalText>
  <!-- @@@ B.4.k.9.r.2.r.2: Method of assessment -->
</methodCode>
- <author>
- <assignedEntity>
  - <code nullFlavor="OTH">
    <originalText>企業</originalText>
    <!-- @@@ B.4.k.9.r.2.r.1: Source of assessment -->
  </code>
  </assignedEntity>
  </author>
- <derivedFrom>
- <implicatedActReference>
  <id extension="d3" root="0.2.999.1.0.5" />
</implicatedActReference>
</derivedFrom>
</reactionRelatedness>
</derivation>
</reaction>
</trigger>
- <trigger>
- <reaction>
  <id extension="r2" root="0.2.999.1.0.5" />
  <!-- For ActReference -->
  <code code="ADVERSE_REACTION" />
- <value code="10049771" xsi:type="CE" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70">
  <!-- @@@ B.4.k.9.r.1a: MedDRA version for Reaction(s)/event(s) assessed -->
  <!-- @@@ B.4.k.9.r.1b: Reaction(s)/event(s) assessed -->
</value>
- <derivation>
- <reactionRelatedness>
  <value xsi:type="ST">不明</value>
  <!-- @@@ B.4.k.9.r.2.r.3: Result -->
- <methodCode nullFlavor="OTH">
  <originalText>全体的な観察評価</originalText>
  <!-- @@@ B.4.k.9.r.2.r.2: Method of assessment -->
</methodCode>
- <author>
- <assignedEntity>
  - <code nullFlavor="OTH">
    <originalText>報告者</originalText>
    <!-- @@@ B.4.k.9.r.2.r.1: Source of assessment -->
  </code>
  </assignedEntity>
  </author>
- <derivedFrom>
- <implicatedActReference>
  <id extension="d3" root="0.2.999.1.0.5" />
</implicatedActReference>
</derivedFrom>
</reactionRelatedness>
</derivation>
- <derivation>
- <reactionRelatedness>
  <value xsi:type="ST">不明</value>
  <!-- @@@ B.4.k.9.r.2.r.3: Result -->
- <methodCode nullFlavor="OTH">
  <originalText>全体的な観察評価</originalText>
  <!-- @@@ B.4.k.9.r.2.r.2: Method of assessment -->
</methodCode>
- <author>
- <assignedEntity>

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- <code nullFlavor="OTH">
  <originalText>企業</originalText>
  <!-- @@@ B.4.k.9.r.2.r.1: Source of assessment -->
</code>
</assignedEntity>
</author>
- <derivedFrom>
- <implicatedActReference>
  <id extension="d3" root="0.2.999.1.0.5" />
</implicatedActReference>
</derivedFrom>
</reactionRelatedness>
</derivation>
</reaction>
</trigger>
- <trigger>
- <reaction>
  <id extension="r3" root="0.2.999.1.0.5" />
  <!-- For ActReference -->
  <code code="ADVERSE_REACTION" />
- <value code="10019663" xsi:type="CE" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70">
  <!-- @@@ B.4.k.9.r.1a: MedDRA version for Reaction(s)/event(s) assessed -->
  <!-- @@@ B.4.k.9.r.1b: Reaction(s)/event(s) assessed -->
</value>
- <derivation>
- <reactionRelatedness>
  <value xsi:type="ST">不明</value>
  <!-- @@@ B.4.k.9.r.2.r.3: Result -->
- <methodCode nullFlavor="OTH">
  <originalText>全体的な観察評価</originalText>
  <!-- @@@ B.4.k.9.r.2.r.2: Method of assessment -->
</methodCode>
- <author>
- <assignedEntity>
  - <code nullFlavor="OTH">
    <originalText>報告者</originalText>
    <!-- @@@ B.4.k.9.r.2.r.1: Source of assessment -->
  </code>
  </assignedEntity>
</author>
- <derivedFrom>
- <implicatedActReference>
  <id extension="d3" root="0.2.999.1.0.5" />
</implicatedActReference>
</derivedFrom>
</reactionRelatedness>
</derivation>
- <derivation>
- <reactionRelatedness>
  <value xsi:type="ST">不明</value>
  <!-- @@@ B.4.k.9.r.2.r.3: Result -->
- <methodCode nullFlavor="OTH">
  <originalText>全体的な観察評価</originalText>
  <!-- @@@ B.4.k.9.r.2.r.2: Method of assessment -->
</methodCode>
- <author>
- <assignedEntity>
  - <code nullFlavor="OTH">
    <originalText>企業</originalText>
    <!-- @@@ B.4.k.9.r.2.r.1: Source of assessment -->
  </code>
  </assignedEntity>
</author>
- <derivedFrom>
- <implicatedActReference>
  <id extension="d3" root="0.2.999.1.0.5" />
</implicatedActReference>
</derivedFrom>
</reactionRelatedness>
</derivation>
</reaction>
</trigger>
- <trigger>
- <reaction>
  <id extension="r4" root="0.2.999.1.0.5" />
  <!-- For ActReference -->
  <code code="ADVERSE_REACTION" />
- <value code="10040070" xsi:type="CE" codeSystemVersion="12.0" codeSystem="2.16.840.1.113883.6.70">
  <!-- @@@ B.4.k.9.r.1a: MedDRA version for Reaction(s)/event(s) assessed -->
  <!-- @@@ B.4.k.9.r.1b: Reaction(s)/event(s) assessed -->

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